Federal Register

Monday,
December 22, 2003

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require the semiannual publication of an inventory of all rulemaking actions under development or review, known as the regulatory agenda. The purpose of this effort is to encourage public participation in the regulatory process by providing, at an early stage, summarized information about regulatory actions that the Department is working on. Citizens interested in communicating to the Department their views on the rulemakings prospectively outlined below are invited to do so.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided below reflects an effort to present for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of a notice of proposed rulemaking, or a final rule within the next 12 months. Also included in the Long-Term Action sections below are summaries of actions that are under development, but which we will probably not complete within the next 12 months.

We welcome hearing the views of all concerned with regard to these planned regulatory or deregulatory actions. Comments may be directed to the agency officials cited in each of the summaries. Or, if early attention at the Secretary#146;s level is seen as warranted, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

The Office of Management and Budget requires that fall editions of the agenda be augmented by a regulatory plan, highlighting the most important regulatory issues across the executive branch. The HHS portion of the Plan appears in part II of this issue of the **Federal Register** with those of other Departments and Agencies. Our Plan entries are included in the table of contents below, denoted by a bracketed bold reference to the appropriate sequence number in part II.

Dated: October 17, 2003.

Ann C. Agnew,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
961	Safe Harbor for Arrangements Involving Federally Qualified Health Centers	0991–AB06
962	Claims Collection	0991–AB18
963	Salary Offset	0991–AB19
964	Health Insurance Portability and Accountability Act–Enforcement **(Reg Plan Seq No. 40)**	0991–AB29

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
965	Shared Risk Exception to the Safe Harbor Provisions	0991–AA91
966	Safe Harbor for Waiver of Beneficiary Coinsurance and Deductible Amounts for a Medicare SELECT Policy	0991–AB16
967	Tax Refund Offset	0991–AB17
968	Implementation of the Equal Access to Justice Act in Agency Proceedings	0991–AB22
969	Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges	0991–AB23

Office of the Secretary—Long-term Actions

Sequence Number	Title	Regulation Identification Number
970	Revisions to Regulations Addressing the OIG's Authority to Impose Civil Money Penalties and Assessments	0991–AB03
971	Amending the Regulations Governing Nondiscrimination on the Basis of Race, Color, National Origin, Handicap, Sex, and Age To Conform to the Civil Rights Restoration Act of 1987	0991–AB10

HHS

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identification Number
972	Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)	0991–AB12

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
973	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth **(Reg Plan Seq No. 41)**	0930–AA10
974	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
975	Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice	0930–AA11

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
976	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
977	Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employee Occupational Illness Compensation Act of 2000	0920–AA07

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identification Number
978	Over-the-Counter (OTC) Drug Review	0910–AA01
979	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) **(Section 610 Review)**	0910–AC58
980	Health Claims	0910–AF09
981	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Derivatives of Blood	0910–AF16

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
982	Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics	0910–AA49

HHS

Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
983	Blood Initiative	0910–AB26
984	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
985	Current Good Manufacturing Practice for Medicated Feeds	0910–AB70
986	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
987	Prevention of Salmonella Enteritidis in Shell Eggs **(Reg Plan Seq No. 42)**	0910–AC14
988	Institutional Review Boards: Registration Requirements	0910–AC17
989	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910–AC19
990	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
991	Exception From General Requirements for Informed Consent; Request for Comments and Information **(Reg Plan Seq No. 43)**	0910–AC25
992	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
993	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs **(Reg Plan Seq No. 44)**	0910–AC35
994	Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements	0910–AC50
995	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
996	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
997	Food Standards: General Principles and Food Standards Modernization	0910–AC54
998	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
999	Revision of the Requirements for Spore-Forming Microorganisms	0910–AC57
1000	Reporting Information Regarding Falsification of Data	0910–AC59
1001	Definition of ''Serious Adverse Health Consequences'' Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 45)**	0910–AF06
1002	Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water	0910–AF10
1003	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
1004	Cochineal Extract and Carmine Label Declaration	0910–AF12
1005	Charging for Investigational Drugs	0910–AF13
1006	Treatment Use of Investigational Drugs	0910–AF14
1007	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
1008	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol **(Reg Plan Seq No. 46)**	0910–AF18

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1009	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910–AA04
1010	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
1011	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910–AA89
1012	Labeling for Human Prescription Drugs; Revised Format **(Reg Plan Seq No. 47)**	0910–AA94
1013	Safety Reporting Requirements for Human Drug and Biological Products **(Reg Plan Seq No. 48)**	0910–AA97
1014	Supplements and Other Changes to an Approved Application	0910–AB61
1015	CGMP for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback) **(Reg Plan Seq No. 49)**	0910–AB76
1016	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 50)**	0910–AB88
1017	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910–AB91
1018	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
1019	Bar Code Label Requirements for Human Drug Products and Blood **(Reg Plan Seq No. 51)**	0910–AC26
1020	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
1021	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
1022	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 52)**	0910–AC38

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identification Number
1023	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 **(Reg Plan Seq No. 53)**	0910–AC39
1024	Registration of Food and Animal Feed Facilities	0910–AC40
1025	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
1026	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910–AC43
1027	Presubmission Conferences	0910–AC44
1028	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AC56
1029	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-term Actions

Sequence Number	Title	Regulation Identification Number
1030	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue–Based Products	0910–AB27
1031	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products Establishments; Inspection and Enforcement	0910–AB28
1032	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
1033	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identification Number
1034	Investigational Use New Animal Drug Regulations **(Completion of a Section 610 Review)**	0910–AB02
1035	Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims	0910–AB66
1036	Aluminum in Large- and Small-Volume Parenterals Used in Total Parenteral Nutrition	0910–AC18
1037	Regulation of Carcinogenic Compounds Used in Food-Producing Animals; Definition of ''No Residue''	0910–AC45
1038	Applications for FDA Approval To Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications	0910–AC48

Health Resources and Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identification Number
1039	National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements	0906–AA41
1040	Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906–AA44

Health Resources and Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identification Number
1041	Interim Final Rule for the Smallpox Emergency Personnel Protection Program: Smallpox (Vaccinia) Vaccine Injury Table	0906–AA60
1042	Smallpox Vaccine Injury Compensation Program: Administrative Implementation **(Reg Plan Seq No. 54)**	0906–AA61

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Prerule Stage

978. OVER-THE-COUNTER (OTC) DRUG REVIEW

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 350

Legal Deadline: None

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Anorectal Products (0910–AC65)
Final Action (Amendment) 08/26/03 (68 FR 51167)
Antidiarrheal Products (0910–AC82)
NPRM (Amendment) (Trav. Diar) 04/17/03 (68 FR 18915)
Final Action (Amendment) (Trav. Diar) 04/00/04
Antiemetic Products (0910–AC71)
Final Action (Amendment) (Warning) 12/06/02 (67 FR 72555)
Antiperspirant Products (0910–AC89)
Final Action 06/09/03 (68 FR 34273)
Cough/Cold (Antihistamine) Products (0910–AD31)
Final Action (Amendment)(Common Cold) 04/00/04
Cough/Cold (Antitussive) Products (0910–AD24)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Cough/Cold (Bronchodilator) Products (0910–AD33)
NPRM (Amendment) 06/00/04
Cough/Cold (Combination) Products (0910–AD25)
Final Action 12/23/02 (67 FR 78158)
NPRM (Amendment) 06/00/04
Cough/Cold (Nasal Decongestant) Products (0910–AD43)
NPRM (Phenylephrine Bitartrate) 04/00/04
NPRM (Phenylpropanolamine) 04/00/04
NPRM (Amendment) (Sinusitis Claim) 06/00/04
External Analgesic Products (0910–AD06)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
NPRM (Amendment) (Patches) 07/17/03 (68 FR 42324)
Ingrown Toenail Relief Products (0910–AD21)
NPRM 10/04/02 (67 FR 62218)
Final Action 05/07/03 (68 FR 24347)
Internal Analgesic Products (0910–AD07)
NPRM (Amendment)(Ibuprofen) 08/21/02 (67 FR 54139)
NPRM (Amendment) (Labeling) 04/00/04
NPRM (Amendment) (Pediatric) 04/00/04
Labeling of Drug Products for OTC Human Use (0910–AD47)
NPRM (Convenience Sizes) 02/00/04
NPRM (Sodium Labeling) 02/00/04
Final Action (Sodium Labeling) 02/00/04
Final Action (Ca/Mg/K/Na) 02/00/04
Laxative Drug Products (0910–AC85)
NPRM (Amendment) (Psyllium Granular Dosage Form) 08/05/03 (68 FR 46133)
Nighttime Sleep Aid Products (0910–AD11)
Final Action (Amendment)(Warning) 12/06/02 (67 FR 72555)
Ophthalmic Products (0910–AC72)
NPRM (Emergency First Aid Eyewashes) 02/19/03 (68 FR 7951)
Final Action (Technical Amendment) 02/19/03 (68 FR 7919)
Final Action (Name Change) 06/03/03 (68 FR 32981)
Oral Health Care Products (0910–AC98)
ANPRM (Plaque/Gingivitis) 05/29/03 (68 FR 32232)
Pediculicide Products (0910–AC79)
NPRM (Labeling Amendment) 05/10/02 (67 FR 31739)
Final Action (Labeling Amendment) 02/00/04
Salicylate (Reye's Syndrome) (0910–AD13)
Final Action (Warning) 04/17/03 (68 FR 18861)
Skin Protectant Products (0910–AC96)
Final Action 06/04/03 (68 FR 33362)
NPRM (Astringent) 06/13/03 (68 FR 35346)
Final Action (Astringent) 06/13/03 (68 FR 35290)
Final Action (Astringent) (Confirm Effective Date) 10/09/03 (68 FR 58273)
Final Action (Technical Amendment) 12/00/03
Sunscreen Products (0910–AC68)
Final Action (Names) 06/20/02 (67 FR 41821)
ANPRM (and Insect Repellent) 04/00/04
NPRM (UVA/UVB) 04/00/04
Vaginal Contraceptive Products (0910–AD19)
NPRM (Amendment) 01/16/03 (68 FR 2254)
Final Action (Warnings) 06/00/04
Weight Control Products (0910–AC93)
NPRM (Phenylpropanolamine) 04/00/04

Regulatory Flexibility Analysis Required: Yes

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827–2241
Fax: 301 827–2315
Email: rachanow@cder.fda.gov

RIN: 0910–AA01

979. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD (PART 110)

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 342; 21 USC 371; 21 USC 374; 42 USC 264

CFR Citation: 21 CFR 110

Legal Deadline: None

Abstract: Part 110 (21 CFR part 110) describes regulations for current good manufacturing practice in manufacturing, packing, and holding human food. Part 110 contains regulations describing sanitary practices for personnel, buildings and facilities, and equipment. It also includes regulations on production and process controls for manufacturing practices and on defect action levels for natural or unavoidable defects in food for human use that present no health hazard. FDA is undertaking a review of part 110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) the continued need for the regulations in part 110; (2) the nature of complaints or comments received concerning the regulations in part 110; (3) the complexity of the regulations in part 110; (4) the extent to which the regulations in part 110 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 110.